

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

HUMAN GENOME SCIENCES, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 08-166-SLR
	)	
GENENTECH, INC.,	)	
	)	
Defendant.	)	

**HGS' ANSWERING BRIEF IN OPPOSITION TO  
GENENTECH'S MOTION TO DISMISS**

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Dated: June 26, 2008

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## INTRODUCTION

Human Genome Sciences (“HGS”) submits this answering brief in opposition to Genentech’s motion to dismiss this case under Fed. R. Civ. P. 12(b)(1) and 12(b)(6), or in the alternative to dismiss or strike specific portions of HGS’ complaint. In the underlying interference, HGS asked the Board to enter adverse judgment against it on the issue of priority after the Board rendered the decisions on substantive motions that are the subject of this action. Here, HGS seeks review of the Board’s decisions on substantive motions under 35 U.S.C. § 146. Genentech argues that this action should be dismissed because, according to Genentech, HGS failed to “exhaust” its administrative remedies by “bypass[ing] the PTO’s administrative procedures,” and “leapfrog[ging] the Board’s consideration of priority.” Genentech is wrong; HGS fully exhausted its remedies before the Board with respect to the decisions appealed in this action, and there exists no factual or legal basis for dismissing the action as requested by Genentech. Accordingly, Genentech’s motion should be denied.

The crux of Genentech’s argument is that by seeking adverse judgment on the issue of priority after the Board rendered its decisions on substantive motions, HGS denied the Court “the benefits of the Board’s technical and legal expertise.” (Br. at 11). However, with respect to the decisions on substantive motions appealed in this case, such “benefits” are illusory because the Board would not have reviewed those decisions further in the remaining portion of the interference. Assuming that HGS had gone forward with the priority phase of the interference before the PTO and then had simply not appealed the decision on priority *per se* in a later § 146 action, the issues on appeal under § 146 (*i.e.*, the decisions on substantive motions) would have been *identical* to what they are in the present action. In other words, HGS pursuing the priority case before the Board would have resulted in *no change whatsoever* to the issues on appeal under

§ 146 because the Board does not revisit its prior decisions on substantive motions during the priority phase.

Moreover, as discussed in detail below, a reversal by the Court of the decisions appealed here moots—and, in fact, renders irrelevant—the particular proofs that were mandated by the Board’s decisions on, for example, the issue of “benefit,” during the substantive motions phase. (*See infra* at B.1). HGS conceded that if the Board’s decisions on substantive motions are affirmed, HGS will not prevail on the particular priority proofs that were dictated by the Board’s decisions, in particular, the decision on benefit. On the other hand, reversal of the benefit decision by the Court in this § 146 action would mandate an entirely new set of factual proofs on the priority issues from both Genentech and HGS. These new factual proofs were not at issue under the Board’s benefit determinations.

Genentech bases its arguments on a distorted view of the “exhaustion” doctrine, but that doctrine in no way supports Genentech’s arguments. To bar a District Court’s jurisdiction, exhaustion of an administrative remedy must be mandated by the statute (so-called “jurisdictional exhaustion”), or the remedy must be required by the courts in order to allow the agency to address the issues in the first instance and “to correct its own errors” (so-called “prudential exhaustion”). *Metropolitan Life Ins. Co. v. Price*, 501 F.3d 271, 279 (3d Cir. 2007). Neither type of exhaustion applies here. First, the statutes in question do not include an exhaustion requirement of any kind, and thus “jurisdictional exhaustion” does not apply. (*See infra* at B.5). Second, after extensive exploration, briefing and argument by the parties, the Board utilized its “special technical and legal expertise” to analyze and decide the issues that are raised in this appeal. There was no other remedy left for HGS to seek from the Board with respect to the issues raised in this appeal. Nor could the Board have reviewed and/or reversed its

decisions on those issues during the later priority phase of the interference. HGS had no other administrative remedies to pursue, and the Board could not have provided the Court with any additional “legal” or “technical” expertise on the questions presented here. Thus, the decisions of the Board were ripe for review by the Court under § 146, and, accordingly, Genentech’s “prudential exhaustion” argument simply does not hold water. (*See infra* at B.2).<sup>1</sup>

HGS is not, as Genentech asserts, asking the Court to “usurp” the Board’s original jurisdiction, and HGS’ actions do not leave room for “mischief.” (Br. at 16–17). This action only requests that the Court rule on issues already addressed and decided by the Board. Such review is unquestionably mandated by § 146. Moreover, HGS will not now, nor will it at any later point in time, seek to enter a priority phase based on the specific benefit decisions that have been made by the Board, which decisions are the subject of this appeal. If the decisions of the Board are affirmed, the question of priority on the basis of those decisions will not be revisited. However, if the benefit decisions of the Board are reversed, and a new benefit decision is made, then a new priority phase can be remanded to the Board, or, if the Court chooses, and at its discretion, heard and decided by the Court.

As discussed in detail below, Genentech’s motion should be dismissed in its entirety.

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<sup>1</sup> Genentech’s position on this issue is the height of irony. After the Board’s decision on the parties’ benefit motions, Genentech filed a request for reconsideration asking for an entry of Judgment in its favor on the issue of priority, arguing that a priority phase was unnecessary in light of the Board’s decisions. (D.I. 11, Ex. 15). In contrast to its present position, Genentech correctly recognized that there was nothing further for the Board to do on the question of benefit in light of the decisions made by the Board on substantive motions, and it argued that the priority determination was dictated by the Board’s decisions. Genentech clearly recognized that HGS had fully exhausted its administrative remedies and Genentech argued that the Board should enter judgment against HGS on the issue of priority without the Board conducting a priority determination. Remarkably, Genentech now argues that the process it told the Board was *unnecessary* (*i.e.*, a priority phase) is *required* before this Court can take jurisdiction over the case.

## **SUMMARY OF THE ARGUMENT**

### **A. “Prudential Exhaustion” Does Not Bar This Action**

HGS is seeking review under § 146 of certain decisions rendered by the Board following full briefing, argument, and presentation of evidence. As far as the Board was concerned, under its own procedures and precedent, these decisions were final and would not be reviewed by the Board during any subsequent proceedings in the interference. Accordingly, no reasonable argument can be made, either legally or factually, that failure to “exhaust” administrative remedies mandates dismissal of this case.

Genentech, however, has concocted a “rule” on “prudential exhaustion” that would force a party to mechanically go through the motions in a priority phase, presenting evidence it knows is insufficient to prevail on the issue of priority, just to have the right to appeal the decisions on substantive motions which defined the impossible priority contest. This is not the law. The steps taken by HGS to seek review of the Board’s decisions parallel the procedure in which a patent litigant receives an adverse claim construction and then concedes infringement in order to appeal the claim construction. This procedure is well-accepted as promoting judicial efficiency. By contrast, Genentech’s proposed rule would waste everyone’s time and resources and makes no sense. Moreover, conducting such a priority contest would not provide a reviewing court any greater insight or narrowing or focusing of the issues, as those issues would not (and could not) be raised again or reviewed during the priority phase. With respect to the issues decided by the Board in the substantive motions phase, further proceedings by the Board would provide nothing to aid in a § 146 review.

**B. “Jurisdictional Exhaustion” Does Not Bar This Action**

Genentech also argues that this case should be dismissed due to a lack of “jurisdictional” exhaustion. However, dismissal of a case for lack of jurisdictional exhaustion is appropriate *only* where there is an express exhaustion requirement in the statutory language which makes clear that exhaustion is a predicate for the District Court to exercise jurisdiction. There is no language in the text of § 146 (or the statutes that Genentech points to, *i.e.*, 35 U.S.C. §§ 6 and 135(a)) that mandate that a party participate in a priority phase in order to take an appeal. Thus, HGS is not barred from this appeal by “jurisdictional exhaustion.”

**C. Genentech’s Motion to Strike HGS’ Specific Requests for Review Should be Rejected**

In the event that the Court rejects its arguments regarding exhaustion, Genentech seeks to dismiss or strike HGS’ requests for review of two additional Board decisions: (i) the Board’s decision not to allow HGS to pursue its claims of invalidity under § 103, and (ii) the Board’s decision not to impose sanctions on Genentech. As discussed below, these arguments do not have merit, nor are they timely brought.

**FACTUAL BACKGROUND**

Since its inception in the early 1990’s, HGS has engaged in active research and development of novel protein and antibody therapeutics. In particular, HGS identified several novel “death receptors,” proteins on the surface of cells that can induce programmed cell death, as targets for the treatment of diseases such as cancer and HIV infection. Among the death receptors identified by HGS by the end of 1996 were receptors designated DR3 and DR4. Prior to March 1997 HGS identified the fifth member of the death receptor family, DR5. On March 17, 1997, HGS filed its first U.S. patent application describing that discovery. HGS filed several

subsequent applications directed to DR5 which specifically incorporated by reference each of the previous patent applications. On May 4, 2000, HGS filed the application that ultimately issued as the involved U.S. Patent No. 6,872,568 (“the ’568 patent”). (D.I. 1, Exh. B).

**A. Interference 105,361**

When two parties claim the same subject matter in U.S. patent applications and patents, the Patent Office institutes a proceeding termed an interference to determine which party invented the subject matter first. An interference proceeds in stages. First, the Patent Office declares the interference. In declaring the interference, the Patent Office specifies the filing dates of patent applications for which each party will be accorded benefit (*i.e.*, effective filing date). The party’s effective filing date sets the lower bound for its possible invention date (*i.e.*, the party’s date of invention is no later than its effective filing date).

On August 31, 2005, the Board declared Interference No. 105,361 (“the ’361 interference”) between HGS’ ’568 patent and Genentech’s pending U.S. Application No. 10/423,448, which was filed on April 25, 2003. (D.I. 11, Exh. 1). The Board indicated that both parties claimed the same patentable invention.<sup>2</sup>

Prior to the substantive motions phase, the Board made a preliminary determination of, *inter alia*, the actual invention involved in the interference by defining a “count,” and decided whether to accord either party “benefit” to its earlier-filed patent applications. *Id.* at 2–3; *see also* 37 C.F.R. §§ 41.201; 41.203(b) (2005). In the context of interference proceedings,

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<sup>2</sup> The Board actually declared four separate interference proceedings involving HGS patents and/or pending patent applications, three involving Immunex and this interference involving Genentech. Only one of these interferences is still pending, whereas the other three are before this Court as § 146 actions. *See* C.A. No. 07-526 (SLR) (sub judice involving Immunex), 07-780 (SLR) (reconsideration of dismissal involving Immunex), 08-166 (SLR) (this case involving Genentech).

“benefit” refers to the earliest patent application that the Board deems that a party is entitled to rely upon as a constructive reduction to practice. 37 C.F.R. § 41.201 (2005).

Neither party was initially accorded its earliest possible benefit date when the interference was declared. Genentech was accorded a benefit date of May 14, 1998, and HGS was accorded its last filing date, May 4, 2000. (D.I. 11, Exh. 1 at 2). Based on the Board’s initial benefit determination, the Board designated Genentech the “senior party” because of its earlier accorded benefit date, and designated HGS the “junior party” because of its later accorded benefit date. *Id.* The accorded benefit dates determined not only the earliest constructive reduction to practice dates for each respective party, but also the allocation of burdens of proof for the priority phase. 37 C.F.R. § 41.207(a) (2005) (“Parties are presumed to have invented interfering subject matter in the order of the dates of their accorded benefit for each count.”). The Board’s decision on benefit is significant to the subsequent priority phase because it defines the parameters under which the question of priority of invention will be analyzed.

As a result of the Board’s initial benefit determination, Genentech was presumed to be the first inventor unless HGS could show during the substantive motions phase that it should be accorded an earlier benefit date.

During the substantive motions phase, HGS challenged the Board’s initial benefit determinations, as well as the definition of the count.<sup>3</sup> (D.I. 11, Exhs. 2 and 3). HGS filed its Substantive Motion 3 on December 8, 2005. (Exhibit A to Declaration of A. Antony Pfeffer).<sup>4</sup> In that motion, HGS explained that although HGS’ patent-in-interference was filed on May 4,

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<sup>3</sup> For the sake of convenience, HGS focuses primarily on the Board’s decision determining benefit. However, during the substantive motions phase the Board rendered decisions on several other issues as well.

<sup>4</sup> Unless otherwise indicated, exhibits mentioned in this brief are attached to the Declaration of A. Antony Pfeffer in support of HGS’ answering brief.

2000, HGS had filed six earlier and related applications directed to its invention, the first of which was filed on March 17, 1997. HGS argued that it was entitled to rely upon these earlier filed applications, as each met the requirements of, *inter alia*, § 112. Accordingly, HGS explained that it was entitled to rely upon these applications, including the earliest of the applications, as a constructive reduction to practice. HGS' Substantive Motion 3 involved 44 exhibits (*id.* at 27–28) and 74 factual statements (*id.* at 29–46), and relied upon the expert testimony of John Reed, M.D., Ph.D. (Exh. B). Genentech opposed HGS' motion with its own expert declarant, Dr. Michael Karin, and proffered an additional 259 facts. (Exh. C). HGS submitted its reply brief (Exh. D), and the Board heard final arguments on the issue. (Exh. E).

#### **B. The Board's Decisions on Substantive Motions**

On November 28, 2007, the Board rendered its decision on substantive motions, denying HGS' motion for benefit to its earlier applications. (D.I. 11, Exh. 5). As is the case in many interferences, the decision on substantive motions effectively dictated the outcome in the interference. *See, e.g., Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318 (Fed. Cir. 2005) (party sought adverse judgment after it was denied benefit to earlier application because it could not prevail on the priority framework defined by the decisions on substantive motions); *Enzo Therapeutics Inc. v. Yeda Research & Dev. Co.*, 477 F. Supp. 2d 699 (E.D. Va. 2007) ("Enzo II"). HGS believes the Board's decision on benefit was factually and legally incorrect and is now seeking review of the decision (along with others) in this action under § 146.

In the priority phase, the parties must demonstrate that they are entitled to priority within the confines of the decisions made by the Board during the substantive motions phase. In the priority contest defined by the Board's decisions in this case, Genentech was granted benefit to a May 14, 1998 application, and HGS was granted benefit to its patent application filed May 4,

2000. As discussed in detail below (*see infra* at B.1), under the Board's decisions, which set the ground rules for the priority contest, it was clear that HGS could not prevail in demonstrating priority of invention. After rendering these decisions, the Board, in fact, instructed HGS to notify the Board if HGS was not going to file a priority motion. (D.I. 11, Exh. 6 at 2:16–18).

After the Board's final decision regarding benefit, Genentech recognized the futility of HGS' priority case based on that decision. Genentech also recognized the finality of the Board's decision regarding benefit with respect to any later phase in the interference. Accordingly, Genentech moved for judgment on the issue of priority, arguing that any attempt by HGS to prevail on priority would be futile. (D.I. 11, Ex. 15). The Board ruled that Genentech's motion was moot when it entered judgment against HGS on the issue of priority. (D.I. 1, Exh. A).

Rather than waste the effort and resources of the parties and the Board, HGS elected not to pursue priority under the Board's benefit decisions. HGS informed the PTO that it would seek review of the earlier decisions of the Board under 35 U.S.C. § 146. (D.I. 11, Exh. 7). However, HGS also requested that it be allowed to brief and seek a determination by the Board on the issue of the invalidity of Genentech's claims under § 102(e) / § 103, and its desire to brief that issue before the Board. *Id.*

On February 20, 2008, the Board entered final judgment awarding priority to Genentech. (D.I. 1, Exh. A). In entering that Judgment, the Board concurrently issued an order denying HGS' request to file the invalidity motion with respect to Genentech's claims in interference. (D.I. 11, Exh. 8).

On March 25, 2008, HGS filed this case under § 146 seeking review of the Board's decisions. (D.I. 1).

## ARGUMENT

### A. The Court Has Jurisdiction to Review the Decisions of the Board Under § 146

This Court unquestionably has subject matter jurisdiction over this case. Section 146 of the Patent Act expressly provides subject matter jurisdiction for district court review of decisions made by the Board: “Any party to an interference *dissatisfied with the decision* of the Board of Patent Appeals and Interferences on the interference may have remedy by civil action.” 35 U.S.C. § 146 (emphasis added). HGS is dissatisfied with certain final decisions of the Board, each of which were specifically identified in HGS’ complaint. (D.I. 1 at ¶¶ 14, 18–23). With respect to those decisions, there is no question that the Court has subject matter jurisdiction. Moreover, although HGS seeks review only of formal Board decisions made during Interference No. 105,361, Federal Circuit precedent holds that a district court may even review issues raised during an interference proceeding for which the Board never provided a formal decision. *Conservolite, Inc. v. Widmayer*, 21 F.3d 1098, 1102 (Fed. Cir. 1994); *see also, General Instrument Corp. v. Scientific-Atlanta, Inc.*, 995 F.2d 209, 214 (Fed. Cir. 1993).<sup>5</sup>

In this case, Genentech does not dispute the fact that HGS is dissatisfied with the Board’s decisions, including, *inter alia*, the decision denying HGS benefit to its earlier-filed patent applications. Genentech also does not dispute the fact that the Board rendered a formal decision denying HGS’ motion for benefit. (D.I. 11, Exh. 5). As such, Genentech does not substantively dispute the two facts relevant to an analysis of subject matter jurisdiction in this case. Genentech

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<sup>5</sup> Often in § 146 actions the question arises as to whether the Court should consider issues which had not been raised below. With respect to those issues never raised below, it is still within the court’s discretion to consider them. *See Conservolite*, 21 F.3d at 1102 (“Under appropriate circumstances, a district court may exercise its discretion and admit testimony on issues even though they were not raised before the Board.”) While precedent indicates that a district court may consider issues *not* raised in an interference, no precedent indicates that a district court may refuse to consider issues fully decided by the Board.

argues instead that the Court lacks jurisdiction because HGS failed to fully exhaust its administrative remedies prior to bringing this action. As detailed below, Genentech's argument fails.

**B. Genentech's Reliance on "Exhaustion" Is Misplaced**

Genentech argues that HGS' complaint should be dismissed under the doctrines of "jurisdictional" and "prudential" exhaustion. According to Genentech, by seeking adverse judgment on the issue of priority and review of the Board's decisions on substantive motions, HGS is "leapfrogging" and "sidestepping" the Board. Further, Genentech asserts that HGS' actions could perhaps "bring an end to the interference practice so carefully set forth in Title 35 of the United States Code." (Br. at 12). While Genentech may be strong on the colorful hyperbole, it is weak on the law. As explained below, the doctrine of exhaustion, jurisdictional, prudential, or otherwise, does not compel dismissal of HGS' complaint. Although there is no exhaustion requirement in the statutes at issue here, there is also no question that HGS fully and completely exhausted all procedural remedies offered by the Board of Patent Appeals and Interferences with respect to the decisions HGS appeals.

**1. HGS Is Appealing the Decisions of the Board on Substantive Motions Which Preordained the Outcome of the Priority Contest**

In this § 146 action HGS is seeking review of the decisions rendered by the Board during the substantive motions phase. Over the course of the underlying '361 interference, the Board issued a number of decisions, the most important of which included the decisions on substantive motions entered on November 28, 2007. (D.I. 11, Ex. 5). These decisions defined the count(s),

fixed the claims designated as corresponding to the count(s), and immutably determined the benefit dates accorded to both HGS and Genentech.<sup>6</sup>

**a. The Board's final decision on "benefit" defined a priority contest that HGS could not win**

The issue of "benefit" in interferences is of particular importance as it establishes the earliest patent application that a party can rely upon as supporting its claims corresponding to the count, and the corresponding date of a constructive reduction to practice. In other words, in making a benefit determination, the Board analyzes whether a party should be allowed to claim earlier patent applications as a constructive reduction to practice of the invention at issue, *i.e.*, whether the party should be granted "benefit" to those applications. The benefit decision (which primarily involves considerations by the Board under 35 U.S.C. § 112) determines the necessary proofs, if any, that each party must make in order to demonstrate "priority" of invention (*i.e.*, which party made the invention first) during the priority phase. The party with the earliest constructive reduction to practice has an easier, oftentimes unassailable, claim to priority.

The priority contest defined by the specific decisions appealed by HGS made it impossible for HGS to prevail on the issue of priority. HGS believes that the Board's decisions were wrongly decided, and that the priority contest the Board defined was factually and legally wrong. If the decisions had been properly rendered, HGS would have been designated the "senior party" in the underlying interference, not Genentech. The priority contest that would be defined if the motions had been properly decided would be so fundamentally different from the one defined by the Board's incorrect decisions as to render meaningless any decisions the Board might have made during the incorrectly-framed priority phase.

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<sup>6</sup> The Board also decided which motions could be filed, whether Genentech should be sanctioned, and the schedule for the priority phase. (D.I. 11, Exhs. 3, 4, 6).

The Board's decision on benefit was the product of extensive exploration, briefing and argument by the parties, and a lengthy written decision by the Board.<sup>7</sup> In HGS' "Substantive Motion 3," HGS sought "benefit" to its earlier-filed patent applications (Exh. A). Genentech opposed the motion (Exh. C), HGS filed a brief in reply (Exh. D), and the Board heard oral argument on the issue. (Exh. E).

The Board rendered its decisions on substantive motions on November 28, 2007. (D.I. 11, Ex. 5). In its decisions, the Board held that HGS' earliest constructive reduction to practice date was May 4, 2000 (*id.* at 12–23), while Genentech was held to have a constructive reduction to practice on May 14, 1998. As mentioned above, this set the stage for a priority contest that HGS could not win. To prevail on priority, a party that has a later reduction to practice must show it has the earliest conception of the invention accompanied with diligence through to its own reduction to practice. Accordingly, to prevail after the Board's benefit decisions, HGS had to prove not only that it conceived of the invention prior to Genentech's accorded benefit date (*i.e.*, at a minimum prior to May 14, 1998), but that it also had exercised reasonable diligence from prior to May 14, 1998 (or an even earlier date of conception if proven by Genentech) to May 4, 2000, a period of almost 2 years. The requirements for such a showing made it impossible for HGS to meet the necessary standard. Because HGS could not make the required showing on conception and diligence, it could not win the priority contest under the Board's decision on benefit.

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<sup>7</sup> In rendering its decisions, the Board is presumed to have performed a careful factual analysis, marshaled the relevant facts and resolved the factual issues in the first instance. *See McGee v. United States*, 402 U.S. 479, 488 (1971).

**b. If the Court reverses or alters the Board's decisions on substantive motions, HGS can win the priority contest**

If the Board had granted HGS' motions on benefit, the priority contest would have been framed very differently and HGS could have prevailed. If the Board had properly analyzed the facts and law in making its decisions on substantive motions, HGS would have been held to have a constructive reduction to practice on (*i.e.*, benefit date of) March 17, 1997, *more than one year prior to Genentech*. Although the Board denied HGS' request for benefit, if the Board had instead accorded HGS benefit to any of its priority applications prior to Genentech's accorded benefit date of May 14, 1998, *the roles of the parties would have switched, making HGS the senior party and Genentech the junior party in the interference*.

In that case, HGS would be presumed to be the first inventor and Genentech would bear the burden of proving that it invented subject matter falling within the count before HGS' accorded benefit date, which should have been March 17, 1997.<sup>8</sup> Specifically, Genentech would have had to proffer evidence that it either (i) conceived of the invention prior to HGS' March 17, 1997 filing date and diligently worked to reduce it to practice, or (ii) actually reduced the invention to practice prior to HGS' filing date. 37 C.F.R. § 41.201. It is HGS' position that Genentech is unlikely to be able to make either showing. However, if Genentech met this initial burden, the burden would have shifted back to HGS to prove an even earlier date.

In its brief, Genentech fails to mention that an entirely new priority case will arise if the Board's "benefit" decisions are reversed by the Court. That entirely new priority case was never presented to the Board, and indeed could not have been presented to the Board because the Board and the parties were bound to follow the decisions the Board makes on substantive

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<sup>8</sup> Although HGS filed a patent application March 17, 1997 that fully supported the claims at issue, the Board ignored it and forced HGS into attempting to prevail in a futile priority battle which had no basis in fact or law.

motions (which at that point were considered final by the Board and binding on its subsequent proceedings) through the priority phase. 37 C.F.R. § 41.2; *Rasmusson v. SmithKline Beecham Corp.*, Inter. No. 104,646, Order Vacating O.C. and Entering Final Judgment (37 C.F.R § 1.658), at \*2–3 (B.P.A.I. Oct. 8, 2003) (noting that ruling of a 3 judge panel is binding in later interference proceedings) (unpublished decision) (Exh. F). It is for this reason that Genentech has filed its motion to dismiss—to avoid having the Court review the Board’s decisions.

**c. The Court can remand to the Board for the priority determination**

Genentech argues that HGS cannot “seek judicial determination of priority in the first instance in the district court.” (Br. at 14). According to Genentech, “HGS simply bypassed Board consideration of priority” and is asking the Court to “conduct an interference in the first instance.” (Br. at 2). This argument is entirely untrue. HGS is not seeking the Court’s determination of priority in the first instance. This Court need not decide the question of who invented the subject matter first, *i.e.*, “priority.” Thus, HGS is *not* asking the Court to replace the Board and conduct the underlying interference. Instead, HGS seeks *review* of the decisions made by the Board during the interference, which review is statutorily mandated by § 146.

If the Court reverses the Board’s decisions on substantive motions it can remand to the Board for a decision on the entirely different facts that would be relevant to a correct priority determination, or—in its discretion—this Court could decide the entirely new question of priority itself. If the Board’s decisions from the substantive motions phase are affirmed, HGS would not contest the “priority” issues it conceded before the PTO, and the Court could affirm the Board’s final judgment.<sup>9</sup>

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<sup>9</sup> This procedure parallels the procedure in which a patent litigant receives an adverse claim construction and then concedes infringement in order to appeal the claim construction. *See, e.g., Schering Corp. v. Amgen Inc.*, 18 F. Supp. 2d 372 (D. Del. 1998) (construing plaintiff-

## 2. HGS Fully Exhausted Its Remedies Before the Board with Respect to the Decisions on Appeal in This Action

When the Board issued its decision denying HGS' request for benefit—two years after declaring the interference—and after the Board entered judgment on priority, neither the Board's Rules of Practice in Patent Cases (37 C.F.R. § 41.200 et al.), nor the Board's Standing Order (Exh. I) required any further action by HGS or the Board before HGS could challenge the Board's decision. Moreover, because the decisions were made by a panel of the Board, the decisions on substantive motions were "final for judicial review." (37 C.F.R. § 41.2).<sup>10</sup> Indeed, in the priority phase, the Board itself would have been bound by its earlier decisions. *Rasmusson*, Order Vacating O.C. and Entering Final Judgment (37 C.F.R. § 1.658), at \*2–3 (Exh. F). To challenge the Board's decision on benefit, HGS could only seek district court review under § 146, or appeal to the Federal Circuit under 35 U.S.C. § 141.

The Board's experience in, and expertise on, the intricacies of interference practice were fully exhausted on the subject of HGS' benefit claim, as well as the issues raised in the other

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Schering's patent claims narrowly), 35 F. Supp. 2d 375 (D. Del. 1999) (granting plaintiff-Schering's motion for summary judgment that Amgen did not infringe Schering's patent under the district court's claim construction), 222 F.3d 1347 (Fed. Cir. 2000) (appealing the district court's claim construction). When claim construction is a prerequisite to the infringement case, the reversal of the claim construction redefines the infringement case. Similarly, if a patent owner receives an adverse benefit decision during an interference, the reversal of the benefit decision redefines the priority case.

<sup>10</sup> A party need not request reconsideration of a Board decision to preserve its rights on appeal. It is settled law that, under the Administrative Procedure Act, the filing of a motion for reconsideration or other appeal to superior agency authority is not a prerequisite to judicial review unless expressly required by statute or rule. *Darby v. Cisneros*, 509 U.S. 137, 154 (1993). It is also well established that a party need not take advantage of agency proceedings that are optional, such as optional motions for reconsideration, in order to satisfy exhaustion requirements. See *Martinez v. United States*, 333 F.3d 1295, 1305-1306 (Fed. Cir. 2003) (noting that under well-settled exhaustion principles, an optional form of administrative relief could not be recrafted by the court into a mandatory prerequisite to suit); *Young v. Reno*, 114 F.3d 879, 882 (9th Cir. 1997) (noting that it would be inconsistent with §10(c) of the APA for courts to require litigants to exhaust optional appeals).

motions. The parties and the Board compiled a massive record on the subject, including full briefs (Exhs. A, C, D), a deposition transcript of Genentech expert (Exh. H), exhibits (Exh. G), a transcript of oral argument (Exh. E), and the Board's 28-page decision on the subject. (D.I. 11, Exh. 5). The Board completed the entire substantive motions phase of the interference proceeding, and set forth the schedule for the priority phase (based on its decisions on substantive motions). Although HGS believes that the Board committed errors in rendering its decisions, the Board's procedural process was fully exhausted, and every purpose behind the doctrine of administrative exhaustion was met in this case. *See Weinberg v. Salfi*, 422 U.S. 749, 765 (1975).

Genentech's hidebound argument is that in order to challenge the Board's decisions on substantive motions, HGS was required to go through the motions of a priority contest that it could not win. But having the parties and the Board engage in a lengthy, expensive, and time consuming priority phase would not provide the Court with meaningful assistance in this § 146 action. As noted above, the Board would not have reconsidered its decisions in the substantive motions phase, including its decision as to the "benefit" date to which HGS was entitled. Instead, the parties and the Board would be engaged in presenting and evaluating evidence regarding when the parties conceived of the invention, whether there was an actual reduction to practice earlier than the constructive reduction to practice (as previously decided by the Board), and the activities between these dates. None of this evidence, nor the Board's evaluations and final decisions on this evidence, have any relevance to the issues upon which the Board ruled in its decisions on substantive motions and as to which review is sought in this §146 action.

Indeed, after receiving the Board's decisions on substantive motions, Genentech itself recognized and advocated that any attempt by HGS to establish priority was futile and would be

a waste of resources, and sought immediate entry of judgment on priority against HGS on the basis of the decisions in the substantive motions phase. (D.I. 11, Exh. 15).

Despite the fact that HGS exhausted administrative remedies on the issue of benefit, Genentech now requests the dismissal of HGS' entire complaint on the basis of "prudential exhaustion." Prudential exhaustion prevents district courts from reviewing issues which should be first decided by an administrative agency. *McGee v. United States*, 402 U.S. 479, 483, n.6 (1971) (the rationale for this doctrine "lies in purposes intimately related to the autonomy and proper functioning of the particular administrative system Congress has constructed."). Here, the Board decided the issues that are to be reviewed by the Court. The Board engaged in a factual analysis, made findings of fact, and applied its special expertise to the decisive substantive motions. HGS seeks review of those decisions. The doctrine of "prudential exhaustion" has no relevance here.

The Court has already grappled with and rejected the underlying premise of Genentech's argument. Although the two arguments are dressed in different legal trappings, "mootness" versus "exhaustion," the mootness argument made by Amgen and rejected by the Court in the copending case, *Human Genome Sciences, Inc. v. Amgen, Inc.*, has the same premise as the argument made by Genentech, *i.e.*, that HGS is barred from seeking review of the Board's decisions on substantive motions because HGS sought adverse judgment on the issue of priority instead of participating in a futile priority contest. No. 07-780, 2008 U.S. Dist. LEXIS 38464 (D. Del. May 9, 2008). There, the Court ruled that HGS' appeal was not rendered moot by HGS seeking entry of judgment from the Board on the issue of priority. *Id.* at \*22. Although Genentech styles the argument as one concerning "exhaustion," it is essentially the same erroneous argument.

### 3. **The Procedural Steps Taken by HGS to Obtain Judicial Review of the Board's Decisions Have Been Accepted by the Board and the Courts**

A party is permitted to request adverse judgment on priority, thereby admitting that, *based on the Board's particular decisions on substantive motions*, the party will lose the priority contest regardless of the papers filed and arguments made by the parties during the priority phase. The particular decisions made by the Board on substantive motions can then be immediately appealed, and, if the decisions are reversed, a new priority phase can begin. This is what HGS did in this case.

The procedural steps used by HGS to avoid having to present an impossible priority case have been accepted by both the Board and the courts in other cases. It is evident from these cases that the Board need not consider a fully briefed priority phase in order to confer jurisdiction to a district court in a § 146 action, and that such a requirement would needlessly expend the resources of the parties and the Board. For example, in *Enzo Therapeutics, Inc. v. Yeda Research & Dev. Co.*, 467 F. Supp. 2d 579 (E.D. Va. 2006) (“Enzo I”), the Board denied Enzo’s motion to be accorded benefit to an earlier filed application. *Enzo I*, 467 F. Supp. 2d at 582–83. In view of the Board’s decision, Enzo requested adverse judgment on priority, and subsequently filed a § 146 action to appeal the Board’s benefit decision, naming both the Director of the U.S. Patent and Trademark Office (“PTO”) and Yeda as defendants. *Id.* at 584. Reviewing the Board’s decisions, the district court ultimately held on summary judgment that the Board had erred in denying Enzo’s benefit motion and remanded the case back to the Board. *Enzo II*, 477 F. Supp. 2d at 717–18. Although the district court justified its decision to remand to the Board—as opposed to keeping jurisdiction and deciding the remaining issues itself—in order to “take advantage of the Board’s specialized knowledge of the complex patent issues in dispute” (*Id.* at 710), the district court never suggested that it lacked jurisdiction to consider the remaining

issues in the case.<sup>11</sup> At the most basic level, the *Enzo* case stands for the proposition that, upon obtaining a final judgment on priority—even where the parties never briefed the priority phase of the interference—the Board’s decisions on substantive motions are subject to review in a § 146 action.

In another case, junior party Rasmusson appealed the Board’s decision on substantive motions denying it benefit (just like the Board’s decision in this case) after deciding not to assert a priority contest. *Rasmusson*, Order Vacating O.C. and Entering Final Judgment (37 C.F.R. § 1.658), at \*2–3 (Exh. F); *Rasmusson*, 413 F.3d 1318, 1322. During the substantive motions phase of the underlying interference, the Board denied Rasmusson’s request for benefit to eight earlier-filed applications. Left with an impossible priority case and the burden of proof on priority, Rasmusson chose not to assert a priority contest at all. In view of Rasmusson’s failure to put forth a priority case, the Board issued an order to show cause why judgment should not be entered against it. In a subsequent conference with the Board, Rasmusson expressed its concern that “it felt required to file a final brief and request a final hearing in order to have a ‘final’ decision from the Board for purposes of appeal.” *Rasmusson*, Order Vacating O.C. and Entering Final Judgment (37 C.F.R. § 1.658), at \*3 (Exh. F). Recognizing that Rasmusson wished to appeal the Board’s decision denying it benefit and that filing a priority brief would not add

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<sup>11</sup> Neither the district court nor the parties questioned subject matter jurisdiction or whether *Enzo* stated a claim against Yeda. *Enzo I*, 467 F. Supp. 2d at 596. Nonetheless, this Court has indicated that the District Court of the Eastern District of Virginia in *Enzo II* “delineated the scope of its jurisdiction in terms of exhaustion of administrative remedies.” *Human Genome Sciences*, No. 07-780, 2008 U.S. Dist. LEXIS 38464, at \*21–22. The Virginia District Court never considered jurisdiction; it was merely deciding whether to keep or remand the remaining issues. By reversing the Board on the benefit issue, the Virginia District Court was faced with a new issue never considered by the Board. In that situation, it made sense to remand the issue. Similarly, in this case, if the Court reversed the Board’s decision on benefit, it could remand the priority contest to the Board.

anything new to the interference, the Board issued a final judgment against Rasmusson on priority and stated:

The proceeding is not being prematurely interrupted. Rather, termination of the interference at this point is consistent with securing ‘the just, speedy, and inexpensive determination’ of the interference by avoiding needlessly subjecting the parties to redundant and unnecessary expenditures of time, effort and money. 37 C.F.R. § 1.601. Indeed, there are no issues remaining for us to decide. In other words, the necessary factual background has been fully developed and the Board has exercised its discretion and applied its expertise. *Going forward with a final briefing and final hearing where nothing new is being added and priority is not being determined does not improve the efficiency of the administrative process and needlessly expends the resources of the parties and the Board.*

*Id.* at \*6–7 (emphasis added). With the final judgment, Rasmusson appealed the Board’s decision denying Rasmusson benefit to the Federal Circuit under 35 U.S.C. § 141.<sup>12</sup>

#### **4. The Cases Cited by Genentech Do Not Support Dismissing This Action**

The doctrine of administrative exhaustion is inextricably tied to the “particular administrative scheme at issue.” *Weinberg*, 422 U.S. at 765 (citing *Parisi v. Davidson*, 405 U.S. 34 (1972) and *McKart v. United States*, 395 U.S. 185 (1969)). The cases cited by Genentech involve review of administrative agencies other than the Board of Patent Appeals and Interferences, including the Selective Service Board and the International Trade Commission. The procedural remedies offered by these other administrative agencies are different from those of the Board. Apart from the *Human Genome Sciences v. Amgen* § 146 case (C.A. No. 07-780), which was heard by this Court, and is the subject of a request for reconsideration, Genentech cites no case in which a district court has dismissed the entirety of a § 146 action based on a

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<sup>12</sup> The fact that the interference party in *Rasmussen* appealed to the Federal Circuit in a § 141 action instead of a district court in a § 146 action offers no distinguishable difference for the purpose of a subject matter jurisdiction analysis.

party's failure to exhaust administrative remedies before the Board. Although Genentech cites a number of cases dealing with the doctrine of prudential exhaustion, none of Genentech's cases deal with the particular administrative scheme for interference practice before the Board of Patent Appeals and Interferences.

For example, Genentech relies on *McGee*, which deals with the Selective Service Board's ("SSB") denial of the plaintiff's status as a conscientious objector during the Vietnam war. *McGee*, 402 U.S. at 480. In that case, the plaintiff failed to provide the SSB with information related to his claim and refused to participate in any administrative proceedings. *Id.* at 481–82. Not only is the regulatory scheme of the SSB distinct from the Board of Patent Appeals and Interferences, but unlike the plaintiff in *McGee*, HGS vigorously participated in the interference proceeding for over two years and provided the Board with all the relevant information to decide the issue of benefit. Thus, the *McGee* case is inapposite.

In *Corus Staal BV v. United States*, 502 F.3d 1370 (Fed. Cir. 2007), the International Trade Commission ("ITC") issued an unfavorable ruling against the plaintiff. Unlike the Board of Patent Appeals and Interferences, the regulations of the ITC expressly required the plaintiff to raise a disagreement over any of the ITC's preliminary decisions at a final phase of the proceeding. *Id.* at 1378–79. Because the plaintiff failed to do so, the Federal Circuit ultimately ruled that the plaintiff denied the ITC an opportunity to correct its own mistakes. *Id.* at 1380. Unlike the ITC's rules, the Board of Patent Appeals and Interference does not have a requirement that disagreements with decisions on substantive motions should be raised during the priority phase of the interference. The substantive motions and priority phases of an interference are independent of one another, and the Board's decisions on substantive motions

are not subject to any further review by the Board. As such, *Corus* is inapposite to the present facts.

In *Republic Indus., Inc. v. Central Penn. Teamsters Pension Fund*, 693 F.2d 290 (3d Cir. 1982), the Multiemployer Pension Plan Amendments Act (“MPPAA”) expressly required a complainant to arbitrate any grievances. The plaintiff in that case ignored the requirement and filed a district court action instead. *Id.* at 292. The case has no relevance here as HGS did not bypass the interference process before filing its § 146 action. And finally, in *Woodford v. Ngo*, 548 U.S. 81 (2006), the Prison Litigation Reform Act expressly required exhaustion of administrative remedies before a prisoner could bring a § 1983 discrimination action against a state prison. *Id.* at 84. The California procedures in question in *Woodford* required a prisoner to file an action within 15 days of the action being challenged. *Id.* at 85–86. The plaintiff in *Woodford* waited six months to file a grievance, and his action was dismissed. *Id.* at 87. This case too has no relevance whatsoever to the present facts.

In each case upon which Genentech relies, the “particular administrative scheme at issue” imposed specific procedures for addressing grievances, and in each case, the plaintiff snubbed those procedures, resulting in the forfeiture of appellate rights. That situation is very different from the one presented here. HGS fully complied with all PTO regulations, Board Rules, and the Board’s Standing Order, and HGS exhausted every procedural remedy available on the substantive motions, including the issue of benefit. In this case, the Board fully exercised its expertise; a massive record was compiled for further judicial review; and the decision was final from the point of view of any further Board action. Although the Board of Patent Appeals and Interferences was prepared to continue with a priority phase in the interference, that priority phase was dictated and defined by the Board’s decisions on substantive motions. In fact,

Genentech does not (and cannot) dispute the fact that HGS had no additional administrative procedural options for challenging the Board's benefit decision.

Genentech also relies on *Consolidated World Housewares Inc. v. Finkle*, 831 F.2d 261 (Fed. Cir. 1987), but that case likewise sheds no light on the present case. In *Consolidated*, the patentee owned two patents covering the same invention, but naming different inventors. The plaintiff did not request an interference before the Board because it believed that it lacked good cause to obtain an interference judgment. Instead, the patentee filed a district court action. *Consolidated World Housewares Inc. v. Finkle*, 662 F. Supp. 389 (N.D. Ill. 1987). The district court dismissed the action without prejudice ruling that the plaintiff should seek an interference proceeding at the PTO in the first instance. Instead of seeking an interference before the Board, the plaintiff appealed to the Federal Circuit, which agreed that the district court lacked jurisdiction.

Genentech's reliance on *Consolidated* is misplaced. In pertinent part, *Consolidated* stands for the uncontroversial proposition that the Board of Patent Appeals and Interferences should hear interference proceedings in the first instance. Unlike the patentee in *Consolidated*, HGS is *not* seeking to bypass the Board. In this case there was an interference proceeding between HGS and Genentech that lasted two years and resulted in final decisions on substantive motions and a final judgment on priority based on those earlier decisions. Genentech's argument that HGS is trying to bypass the Board's authority to decide priority in the first instance is wrong. HGS is simply seeking review of the decisions rendered by the Board in the underlying interference, decisions based on a fully litigated and developed record. This review is provided by—indeed, mandated by—§ 146. The Court need not make a decision on priority even if it reverses the Board's decisions; priority can be remanded to the Board.

### **5. There Is No Jurisdictional Exhaustion Issue in This Case**

Genentech mistakenly contends that “jurisdictional exhaustion” precludes subject matter jurisdiction in this case. However, the doctrine of “jurisdictional exhaustion” applies only in the context of a statute that expressly mandates exhaustion by the appellant in order to invoke district court review of administrative decisions. Because §§ 6, 135 and 146 do not contain such a mandate, the doctrine of jurisdictional exhaustion has no relevance here.

The Third Circuit recognizes that “jurisdictional” limitations are set by the Constitution or by Congress and not by rules of procedure or judge-made doctrine. *Metropolitan Life*, 501 F.3d at 278. Thus, in this Circuit, a jurisdictional exhaustion requirement must appear in the statutory language, demonstrating that Congress intended to make it a predicate for the District Court’s jurisdiction. *Id.* at 279. The Third Circuit is not alone in this rule. *See, e.g., Paese v. Hartford Life and Accident Ins. Co.*, 449 F.3d 435, 445–56 (2d Cir. 2006) (holding that in the absence of statutory language, failure to exhaust administrative remedies under ERISA was not jurisdictional); *see also, White & Case LLP v. United States*, 67 Fed. Cl. 164, 169 (2005).

Section 146 contains no exhaustion requirement. Section 146 states simply that a party “dissatisfied with the decision of the Board” may have a remedy by civil action. 35 U.S.C. § 146. Here, the Board has rendered decisions with which HGS is dissatisfied, and HGS seeks review of those decisions under § 146. The Court unquestionably possesses subject matter jurisdiction over this case.

Genentech attempts to create a jurisdictional exhaustion requirement from the language of 35 U.S.C. §§ 6 and 135 (which create interference proceedings). Genentech argues that these statutes prevent this Court from reviewing the Board’s decisions on substantive motions unless the Board also determines priority. Genentech conveniently skips over the fact that the Board *entered a judgment of priority* in this case. However, presumably Genentech is arguing that

subject matter jurisdiction is predicated on the Board entering judgment on a fully briefed and argued priority record. Genentech rests its argument on a creative reading of the word “shall.”

Section 135(a) states: “The Board of Patent Appeals and Interferences shall determine questions of priority of the inventions and may determine questions of patentability.” The mandate that the Board “shall” determine priority has absolutely nothing to do with the jurisdiction of district courts to review Board decisions, but rather, it ensures that the Board does not use § 135 to construct a regulatory scheme for *inter partes* opposition proceedings.<sup>13</sup> Genentech argues that the word “shall” is the type of “sweeping and direct” language that Congress uses when it intends to convey administrative exhaustion as a predicate to judicial review. (Br. at 12). Of course, it is nothing of the sort. The statute relied on by Genentech simply says the Board shall determine questions of priority. The statute does not say anything about exhaustion or administrative actions that must be undertaken in order to invoke the Court’s jurisdiction. In particular, there is no statutory requirement that interference parties must participate in a priority phase before they may bring a § 146 action. Furthermore, courts cannot impose additional exhaustion requirements beyond those set forth in the statutes providing review of administrative decisions. *Darby v. Cisneros*, 509 U.S. 137, 154 (1993) (“Courts are not free to impose an exhaustion requirement as a rule of judicial administration where the

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<sup>13</sup> Before 1984, the Board of Patent Appeals and Interferences *only* determined issues of priority, and did not consider issues of patentability. Congress modified § 135 to allow the Board to also determine issues of patentability. Patent Law Amendments Act of 1984, Pub. L. 98-622, 98 Stat. 3383 (1984). To prevent interference proceedings from creating a new basis for a party to challenge another’s patentability, Congress dictated that the Board should determine “priority,” thereby ensuring that priority of invention remained the centerpiece of interference proceedings.

agency action has already become “final” under § 10(c) [of the APA, 5 U.S.C.S. § 704]”).<sup>14</sup>

“Jurisdictional exhaustion” is simply not a relevant consideration in this case.

#### **6. Timely Review of Decisions by the Board on Substantive Motions Serves the Interests of Efficiency**

Interference parties should not be forced to litigate a priority phase when the Board’s decisions on substantive motions render futile one party’s case. In a situation where a party finds itself facing an impossible priority contest, it makes little sense to force it to file pro forma motions, attend a hearing, and await a decision from the Board on a priority contest that it believes to have been wrongly defined from the start. *Weinberg*, 422 U.S. at 775–76 (“Once a benefit applicant has presented his or her claim at a sufficiently high level of review to satisfy the . . . administrative needs, further exhaustion would not merely be futile for the applicant, but would also be a commitment of administrative resources unsupported by any administrative or judicial interest.”); *Rasmusson*, Order Vacating O.C. and Entering Final Judgment (37 C.F.R. § 1.658) (Exh. F).

Simply stated, the rule of law propounded by Genentech wastes everyone’s time. If the Court adopts Genentech’s rationale, the Board and interference parties will be forced to needlessly litigate *meaningless issues* just to preserve their ability to seek review of *other decisions*. This would be analogous to requiring an alleged patent infringer to litigate a non-infringement case after receiving an unfavorable claim construction, even though the alleged infringer has no colorable non-infringement position under the claim construction. Even if the party had no good faith belief in its non-infringement position, the Court would mandate that the party nonetheless litigate the issue vigorously, or else, the party would forfeit all rights to

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<sup>14</sup> The Supreme Court has held that the Administrative Procedure Act (APA), 5 U.S.C. § 706, sets forth standards governing judicial review of findings of fact made by the U.S. Patent and Trademark Office. *Dickinson v. Zurko*, 527 U.S. 150 (1999).

challenge the infringement claim, even if the claim construction was reversed. Genentech's proposed rule makes no sense.

Contrary to Genentech's sweeping and unsupported assertions, providing HGS its statutory right to obtain review of the Board's decisions will not result in the demise of Interference practice.<sup>15</sup> (Br. at 17). During the interference, HGS submitted voluminous evidence to the Board, and argued its case at an oral hearing. The Board then applied its unique expertise to render a decision based on the facts submitted by both parties. It is clear, therefore, that HGS did not seek to "by-pass," "leapfrog" or "sidestep" the Board, but merely sought to avoid wasting the parties' and the Board's time and resources by presenting an impossible priority case. Section 146 unequivocally mandates review of the Board's decisions and that is what HGS seeks.

**C. Genentech's Requests for Dismissal of HGS' Specific Claims Regarding § 103 and Sanctions Against Genentech Should be Rejected**

Genentech has also requested that the Court dismiss HGS' request for review of two decisions of the Board: (i) the Board decision precluding HGS the opportunity to file a motion for invalidity of Genentech's claims under 35 U.S.C. § 103 (in combination with § 102(e) art), and (ii) the Board decision dismissing HGS' motion for sanctions against Genentech. On both of

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<sup>15</sup> Genentech argues that by avoiding the presentation of an impossible priority case HGS has engaged in a "deliberate flouting of administrative processes." Genentech Brief at 12. This assertion is clearly untrue. Far from "flouting" the Board process, HGS engaged in the interference process for two years, and it now seeks expeditious review of the decisions on substantive motions made by the Board during that time. This can hardly be considered "flouting" of the Board's process. The Supreme Court has cautioned against the type of embellishment Genentech is engaged in, stating that "the fear of frequent and deliberate flouting can easily be overblown, since in the normal case a registrant would be 'foolhardy' indeed to withhold a valid claim from administrative scrutiny." *McGee*, 402 U.S. at 485. The Supreme Court's observation is applicable here. A party would be "foolhardy" indeed to seek adverse judgment, and thereby waive the right to present priority evidence under the specific priority case defined by the Board's rulings on substantive motions, unless it was essentially impossible for the party to prevail in the priority phase as defined by the Board.

these issues, HGS sought a ruling from the Board, and the Board rendered a decision for which HGS is dissatisfied. Accordingly, both issues are ripe for review in this § 146 action.

**1. The Board's Decision Denying HGS the Right to Make a Motion Under Section 103 Is Appropriate for Review by the Court**

Genentech moves to dismiss HGS' count seeking reversal of the Board's decision denying HGS' request to file a motion for invalidity of Genentech's involved claims under 35 U.S.C. § 102(e) and obviousness under 35 U.S.C. § 103. Genentech's request should be denied.

During the substantive motions phase of the underlying interference, HGS requested authorization to file a motion challenging the validity of Genentech's patent claims (D.I. 11, Exh. B), which the Board denied. (D.I. 11, Exh. 3 at 3). After the Board's final decisions on substantive motions, HGS again renewed its request for file a motion to invalidate Genentech's patent claims. (D.I. 11, Exh. 7 at 1:14–16). The Board again denied HGS' request and entered final judgment. (D.I. 1, Exh. A). In its Complaint under § 146, HGS alleged that it was dissatisfied with the Board's decisions dismissing HGS' requests and sought review by the district court. (D.I. 1 at ¶¶ 14(e); 18; 23(f)); 23(q)).

There is no basis to dismiss the claim under Rule 12(b)(6) or 12(b)(1). Genentech does not dispute that the Board rendered a decision on an issue raised by HGS, or that HGS is dissatisfied with that decision — which constitutes the sole prerequisites for subject matter jurisdiction. 35 U.S.C. § 146. Genentech conflates the *Conversolite* line of cases (dealing with a district court's decision whether to consider an issue from an interference *not decided* by the Board) with subject matter jurisdiction (dealing with the review of Board *decisions*). There is no logical basis to challenge either subject matter jurisdiction of HGS' claim or the fact that the claim was well-pled. In fact, there is legal precedent stating that a district court can even consider undecided issues raised during the interference. *Conservolite*, 21 F.3d at 1102. HGS

was denied the right to file an invalidity motion, and HGS asks this Court to reverse that decision. Genentech's attempt to exclude a 35 U.S.C. § 103 obviousness challenge to its patent claims in this § 146 action would be more appropriately considered in a case management motion, not a motion to dismiss.

**2. The Board's Dismissal of HGS' Motion for Sanctions Is Appropriate for Review by the Court**

Genentech also moves to "dismiss or strike" Paragraph 23(m) and (n) of HGS' Complaint, which seek sanctions against Genentech. There is no basis to dismiss or strike this claim either.

During the underlying interference, the Board authorized HGS to file a motion for sanctions against Genentech (D.I. 11, Ex. 3 at 3), which HGS did. (D.I. 11, Exh. 11).<sup>16</sup> After the interference was declared, HGS learned that Genentech's counsel engaged in repeated *ex parte* communications with Claire Kaufman, the Examiner reviewing HGS' patent application-in-interference, wherein Genentech repeatedly demanded that Ms. Kaufman deny the allowance of HGS' pending claims. By trying to convince Ms. Kaufman to reject HGS' claims, Genentech apparently tried to avoid an interference proceeding with HGS.<sup>17</sup> Genentech's *ex parte* communications violated Disciplinary Rules of the PTO and Rules of Professional Conduct, including Rule 3.5(b) which states that "[a] lawyer shall not . . . communicate ex parte with [a judge or other official] except as permitted by law." Genentech opposed HGS' motion for

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<sup>16</sup> Concurrently with its motion, HGS notified the Office of Enrollment and Discipline of Genentech's legal counsel's conduct which HGS believed amounted to a violation of the PTO's Disciplinary Rules. (D.I. 11, Exh. 16 at Exh. 1).

<sup>17</sup> The Patent and Trademark Office has a formal procedure for third parties to protest an patent application (37 C.F.R. § 1.291), which specifically requires the party to serve the protest on the patent applicant. Disregarding this procedure, Genentech's counsel never provided HGS notice of its communications with Ms. Kaufman about HGS' patent application.

sanctions and told the Board that it was merely attempting to distinguish HGS' patent as prior art—even though HGS' patent had not been cited against Genentech pending claims. HGS filed a reply to Genentech's opposition, and in August 2006, the Board dismissed HGS' motion in a panel decision. (D.I. 11, Exh. 4 at 3). HGS disagreed with the Board's decision, and after the Board entered final judgment in the interference, HGS filed its Complaint seeking review of this decision under 35 U.S.C. § 146.

On May 8, 2008, Genentech informed HGS for the first time that the PTO's Office of Enrollment and Discipline ("OED") did not ultimately sanction Genentech's counsel and Genentech demanded that HGS amend its complaint, threatening to inform the Court of HGS' refusal otherwise. HGS investigated the matter, and requested that Genentech provide HGS (on an attorney eyes only basis) with Genentech's representations to the OED that apparently caused the OED to end its investigation of Genentech's attorneys. Genentech did not cooperate and instead filed this motion.

Genentech's motion to dismiss this portion of HGS' complaint should be denied. First, under Fed. R. Civ. P. 12(b)(6), all material allegations of HGS' complaint are presumed true. *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957). Furthermore, Genentech as movant bears the burden of demonstrating that no claim has been stated. In its Complaint, HGS alleged, *inter alia*, that the Board "erroneously ruled, contrary to fact and law, that... HGS was not entitled to sanctions against Genentech related to Genentech's activities interfering with the ex parte examination of HGS' application which matured into the '569 patent (Paper 96)." (D.I. 1 at ¶ 14(i)). HGS asks this Court to reverse the Board's decision dismissing its request for sanctions. *Id.* at 23(m) and (n). Assuming all statements in HGS' Complaint to be true, HGS asserted a claim for which relief may be granted. The Board rendered a decision during the interference for

which HGS is dissatisfied, HGS has a right to appeal such decisions under § 146, and HGS alleged these facts in its complaint.

Second, Genentech's request to strike HGS' claim under Fed. R. Civ. P. 12(f) lacks merit. Genentech makes the circular argument that this Court should strike HGS' sanction claim because the Board found that Genentech's conduct, even if unethical, would not affect the patentability of HGS' or Genentech's involved claims. Obviously, HGS is seeking review of the Board's decision, and thus, the Board's reasoning cannot form the basis of Genentech's motion to strike. Furthermore, although Genentech claims that the OED determined that Genentech's counsel did not violate the Disciplinary Rules of the PTO, in fact the OED did not make such a determination, but instead found that the record before did not support an "intentional" violation. Moreover, the OED's ruling is distinct from the Board's decision. HGS is appealing the decision of the Board, not the OED, and thus, the OED decision—although possibly pertinent to HGS' decision as to whether it will continue to pursue its claim—is not pertinent to whether HGS' request for sanctions should be dismissed.

### **CONCLUSION**

For the foregoing reasons, HGS respectfully requests the denial of Genentech's motion to dismiss and its motion to strike Paragraphs 23(m) and (n) of HGS' Complaint.

ASHBY & GEDDES

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Dated: June 26, 2008